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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,549	12/05/2003	Mary J. Laughlin	CWR-019292US ORD	1488

68705 7590 11/08/2010

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EXAMINER	
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ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
11/08/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/730,549	LAUGHLIN ET AL.	
	Examiner	Art Unit	
	Lora E. Barnhart	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 October 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,5,10-12,21-43,48,50-54,56,57,62,63 and 67-69* is/are pending in the application.

4a) Of the above claim(s) *5,9,22,37-39,48,50-53,62 and 63* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 4, 10-12, 21, 23-36, 40-43, 54, 56, 57, and 67-69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendments

Applicant's amendments filed 10/27/10 to claims 1, 54, and 57 have been entered. No claims have been canceled or added. Claims 1, 2, 4, 5, 10-12, 21-43, 48, 50-54, 56, 57, 62, 63, and 67-69 remain pending in the current application, of which claims 1, 2, 4, 10-12, 21, 23-36, 40-43, 54, 56, 57, and 67-69 are being considered on their merits. Claims 5, 9, 22, 37-39, 48, 50-53, 62, and 63 remain withdrawn from consideration. References not included with this Office action can be found in a prior action. Any rejections of record not particularly addressed below are withdrawn in light of the claim amendments and applicant's comments.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 4, 10-12, 21, 23-36, 40-43, 54, 56, 57, and 67-69 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Strauer et al. (2002, *Circulation*

106: 1913-1918) taken in view of Shake et al. (2002, *Annals of Thoracic Surgery* 73: 1919-1926), Ueno et al. (U.S. Patent Application Publication 2002/0037278), Kawamoto et al. (2001, *Circulation* 103: 634-637; reference CJJ on 11/13/06 IDS), Itescu (2003, U.S. Patent Application Publication 2003/0199464), and Peichev et al. (2000, *Blood* 95: 952-958; reference CZZZ on 4/26/06 IDS).

Strauer et al. teach isolating bone marrow (BM) from humans (page 1914, column 1, paragraph 5); isolating bone marrow mononuclear cells (BMCs) therefrom; cultivating them overnight in a buffered tissue culture medium comprising autologous serum (page 1914, column 2, paragraph 1), and administering over 10^6 BM-MNCs to the ischemic tissue using a balloon catheter, specifically via intracoronary administration at ischemic myocardium in a subject in need thereof (page 1914, column 2, paragraph 2; page 1915, column 2, paragraph 3). Strauer et al. teach administering between $1.5x10^6$ and $4x10^6$ BM-MNCs 6 or 7 times, *i.e.*, between $9x10^6$ and $2.8x10^7$ BM-MNCs; Strauer et al. also teach that 0.65% of BM-MNCs are $AC133^+$ ($CD133^+$). Therefore, Strauer et al. teach administering between $5.9x10^4$ and $1.8x10^5$ $AC133^+$ EPCs. Strauer et al. teach that said injections resulted in improved cardiac function, cardiac geometry, and contractility (page 1915, column 2). Strauer et al. teach that their BMCs comprise mesenchymal stem cells (MSCs) as well as endothelial progenitor cells (EPCs; page 1916, column 2, paragraph 2).

Strauer et al. do not teach administering a population of cells comprising at least 75% $CD34^+CD133^+$ EPCs, as in claims 1, 54, and 57 and some dependent claims. Strauer et al. do not teach administering cells in the ratios recited in claims 28, 53, 67,

and 68. Strauer et al. do not teach all of the modes of administration recited in claims 29-32. Strauer et al. do not teach coadministering the cells with VEGF or any recombinant polypeptide, as in claims 40-43. Strauer et al. do not teach administering allogeneic EPCs, as in claim 10.

Shake et al. teach isolating MSCs from bone marrow and culturing them such that hematopoietic cells, fibroblasts, and non-MSC adherent cells are washed away, yielding a purified MSC culture (page 1919, column 2, through page 1920, column 1). Shake et al. teach administering said MSCs directly to an infarcted region of heart tissue in recipient pigs (page 1920, column 2). Shake et al. teach that MSCs so administered engraft into the host myocardium, express muscle-specific proteins, and have a beneficial impact on cardiac remodeling after myocardial infarction (page 1923, column 1).

Ueno et al. teach methods for treating ischemic tissues by administering bone marrow mononuclear cells; Ueno et al. teach that the administration may be local or systemic and may be carried out via injection or infusion into arteries or veins, directly into an occlusion, or application into a tissue or organ of interest (paragraphs 0034 and 0035). Ueno et al. teach that large amounts of cells may be administered to patients safely (paragraph 0037) and that the number of cells administered is optimizable (paragraph 0034). Ueno et al. teach coadministering recombinant VEGF with the BMCs (paragraph 0042).

Kawamoto teaches administering expanded endothelial progenitor cells (EPCs) to rats in which myocardial ischemia has been induced. See pages 634-635.

Kawamoto teaches that EPCs so administered promote neovascularization. See pages 636-637.

Itescu teaches methods for regenerating myocardial tissue after ischemic damage by promoting neovascularization with an injection of endothelial progenitor cells (paragraph 0055). The EPCs of Itescu are found in bone marrow (paragraph 0056), express CD34 and CD133 (paragraph 0061), and may be allogeneic with respect to the recipient (paragraph 0057). Itescu teaches that the number of cells administered to the patient may vary (paragraph 0056), as may the location of the injection (paragraph 0061).

Peichev teaches methods for purifying CD34+ CD133+ cells using fluorescence sorting (Figure 2A; Figure 3C). Peichev teaches that AC33 and CD34 are markers of epithelial endothelial progenitor cells (EPCs) (page 955). Peichev teaches that ventricular neo-intima is populated *in vivo* with cells that express CD34 and CD133 (page 956, column 1, and Figure 6).

The independent claims recite the transitional phrase "consisting essentially of." M.P.E.P. § 2111.03 clearly indicates that "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original). "A 'consisting essentially of' claim occupies a middle ground between closed claims that are written in a consisting of' format and fully open claims that are drafted in a 'comprising' format." *PPG Industries v. Guardian Industries*, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-

54 (Fed. Cir. 1998), *et al.* For the purposes of searching for and applying prior art under 35 U.S.C. §§ 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964) *et al.* Since the specification in this case does not particularly point out the basic and novel characteristics of the claimed composition, the phrase "consisting essentially of" in claims 1, 24, 54, and 57 has been interpreted as "comprising" for the purpose of art rejections.

Claims 1 and 57 have been amended to require that the EPCs be "enriched from umbilical cord blood mononuclear cells," which is a product-by-process limitation. The patentability of a product does not depend on its method of production. Kawamoto, Itescu, and Peichev all teach EPCs; the burden shifts to applicant to show that the manner in which the EPCs administered in the method were isolated affects the EPCs' material properties. See M.P.E.P. § 2113.

A person of ordinary skill in the art would have had a reasonable expectation of success in enriching the $CD34^+CD133^+$ EPCs within the BM-MNCs of Strauer et al. at least twofold because Peichev et al. teach methods for enriching such cells using fluorescence sorting. The skilled artisan would have been motivated to enrich the $CD34^+CD133^+$ EPCs in the administered composition of Strauer et al. because

Kawamoto et al. recognized that EPCs promote neovascularization of ischemic tissue; therefore, administering more cells known at the time of the invention to achieve the desired result of Strauer et al. would improve the outcome of the method of Strauer et al.

The person of ordinary skill in the art would have had a further reasonable expectation of success in coadministering the EPCs of Strauer et al. with the purified MSCs of Shake et al. because the cited references teach that both cells promote healing after myocardial infarction. "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted). See M.P.E.P. § 2144.06. Since Shake et al. teach that their MSCs are "purified" after their culturing step, the level of enrichment would have been a matter of routine optimization at the time of the invention, the skilled artisan recognizing that Shake et al. identified a property of MSCs (i.e., cardiac remodeling) and that it would have been desirable to administer as many cells with that property as possible in treating myocardial infarction.

The person of ordinary skill in the art would have had a further reasonable expectation of success in coadministering the VEGF of Ueno et al. with the cells of Strauer et al. and Shake et al. in the method of Strauer et al. because Ueno et al. teach methods for administering recombinant polypeptides and that such polypeptides may be

coadministered with cells. The skilled artisan would have been motivated to include VEGF with the stem cells in the method of Strauer et al. in view of Shake et al. because Ueno et al. teach that VEGF is a growth factor that promotes neovascularization upon administration to a patient.

The person of ordinary skill in the art would have had a further reasonable expectation of success in administering allogeneic cells in the method of Strauer et al. in view of Shake et al. because Itescu teaches that allogeneic EPCs promote neovascularization. The skilled artisan would have been motivated to administer allogeneic EPCs in the method of Strauer et al. in view of Shake et al. for the expected benefit that the pool of donor cells would be dramatically increased in size.

The selection of the mode of administration of the cells in the method of Strauer et al. in view of Shake et al. would have been a routine matter of optimization on the part of the artisan of ordinary skill, said artisan recognizing that Ueno et al. and Itescu both teach that ischemia may be treated bone marrow-derived cells administered in any of a variety of means. A holding of obviousness over the cited claims is therefore clearly required.

The selection of the number of each type of cell to administer in the method of Strauer et al. in view of Shake et al. would have been a routine matter of optimization on the part of the artisan of ordinary skill, said artisan recognizing that Strauer et al., Shake et al., Ueno et al., and Itescu all teach that these numbers may be modified depending on the desired outcome. A holding of obviousness over the cited claims is therefore clearly required.

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was made to enrich the $CD34^+CD133^+$ EPCs from the BM-MNCs of Strauer et al. using the methods of Peichev et al. and administer more such $CD34^+CD133^+$ EPCs with the purified mesenchymal stem cells of Shake et al. in the method of Strauer et al. because Kawamoto et al. and Shake et al. teach that EPCs and MSCs, respectively, promote neovascularization, and Peichev teaches that EPCs express CD34 and CD133. It would have been further obvious to coadminister recombinant VEGF with the cells in the method of Strauer et al. in view of Shake et al. because Ueno et al. teach that VEGF is a growth factor that promotes neovascularization and aids in treating ischemia. It would have been further obvious to administer allogeneic EPCs in the method of Strauer et al. in view of Shake et al. because Itescu teaches that allogeneic EPCs promote neovascularization. Finally, it would have been further obvious to vary the numbers of each type of cell administered and the mode of administration because Strauer et al., Shake et al., Ueno et al., and Itescu concur that these are optimizable variables for the reasons discussed above.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Response to Arguments

Applicant alleges that none of the references teaches the claimed invention. (Reply at 14-20, 26.) Applicant alleges that the examiner has not established that combining the prior art references as set forth in the rejection would improve Strauer's method. (Reply at 20-21.) Applicant alleges that combining the references as the

examiner suggests would destroy the "advantageous properties" of Strauer's method. (Reply at 21-22.) Applicant alleges that the rejection improperly relies on functional equivalence. (Reply at 22-24.) Applicant alleges that the skilled artisan would not have expected success in choosing the fraction(s) of Strauer's mixture to administer. (Reply at 24-28.) Applicant alleges that the claimed invention yields unexpected results. (Reply at 28-30.) These arguments have been fully considered, but they are not persuasive of error; they will be addressed in turn.

Applicant has relied largely on piecemeal analysis of the references.

The discussion at pages 14-20 and 26 of the reply addresses each of the cited references, one by one, and concludes that none of them teaches the full invention. This sort of analysis, as the examiner has pointed out, is not germane to the patentability of claims rejected in view of multiple references under § 103. None of the information at pages 14-20 and 26 discusses the relationships among the six references relied upon in combination in this rejection. For example, applicant notes at page 17 that Peichev does not teach administering CD133+ CD34+ cells (which Peichev recognized as being EPCs), but applicant has not addressed the fact that both Kawamoto and Itescu do teach administering EPCs. Such analysis is critical to overcome this § 103 rejection over a combination of references, taken together.

There is no requirement for the Office to demonstrate that an obvious combination is an improvement over the prior art

Applicant has held the examiner to an improper standard in alleging that the Office action does not "provide an [*sic*] evidence in fact or technical literature" tending to

show that the selection of at-least-75% enriched CD133+/CD34+ cells would constitute an improvement over the prior art. There is no requirement in § 103 or any other statute that only improvements may be considered patentable.

There are no advantageous properties in Strauer's method applicant clearly identifies as being abrogated by the method set forth in the rejection

Applicant refers to the "advantageous properties achieved [in Strauer's method] by using the mixed population of BMCs" and alleges these would be destroyed by administering two components of that mixed population (Shake's MSCs and Kawamoto, Itescu, and Peichev's EPCs), "especially in view of the other cited prior art." Strauer, Shake, Kawamoto, and Itescu's methods are all concerned with treating ischemic tissues and improving cardiac function. It is not clear how the cited secondary references support applicant's conclusion that Strauer's administration of unsorted BMCs (which contain EPCs and MSCs) has some advantage over administering the components of BMCs, since which those secondary references recognized at the time of filing were responsible for the same effect Strauer noticed.

There is no requirement for the prior art to identify a reason to make the specific substitutions contemplated in the rejection

Applicant relies on *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) for the proposition that ". . . it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." This portion of the *KSR* decision discussed the Federal Circuit's "teaching-suggestion-motivation" (TSM) test, which the Supreme

Court considered a "helpful insight." *Id.* In the paragraph of the decision immediately after the one referenced by applicant, however, the Court pointed out, "Helpful insights, however, need not become rigid and mandatory formulas ... The obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents. The diversity of inventive pursuits and of modern technology counsels against limiting the analysis in this way." *Id.* at 419. Therefore, applicant is incorrect in arguing that the prior art must include an explicitly stated motivation for combination; the gist of *KSR* is that no such explicit suggestion need be present in the art for a proper rejection under 35 U.S.C. § 103.

The cited references themselves establish that at the time of the invention, skilled artisans had identified components within BMCs that, when administered to a patient, would treat ischemic heart tissue. Strauer and Ueno teach modifying the number of administered cells. Shake, Kawamoto, and Itescu variously teach that isolated MSCs and EPCs can serve the same function as Strauer's BMCs, which contain MSCs and EPCs. Peichev teaches methods for sorting and enriching. All of Strauer, Shake, Ueno, Kawamoto, and Itescu specifically contemplate treating ischemic heart tissue, and Peichev demonstrates that left ventricle assist devices in the heart become colonized with EPCs. All of the cited references are within the same field of study. Applicant's claimed method is simply a combination and optimization of the teachings of all of the methods.

At the time of the invention, skilled artisans knew that MSCs and EPCs could treat ischemic heart tissue

The basis for applicant's statement at pages 25-26 that "Strauer et al. teach at the time of filing . . . it was unknown which fraction of mononuclear BMCs contribute [*sic*] to regeneration of necrotic myocardium" is completely unclear. Applicant appears to be again evaluating Strauer on its own, not in combination with the other references. Again, Shake identified MSCs as a subpopulation of BMCs capable of treating infarcted heart tissue. Kawamoto identified EPCs as a subpopulation of BMCs capable of the same function. Taken together in view of the art, the art certainly appreciated that EPCs, MSCs, and BMCs were functional equivalents in that they could be administered to a patient to treat ischemic heart tissue. It is not clear what element of the invention applicant considers to be so unpredictable that the skilled artisan would not have reasonably expected success, given the art teachings that each of the elements administered in the claimed method had the claimed effect, as did a composition containing both (Strauer). Applicant has supplied no data showing, for example, that the choice of the degree of purity or the number of cells administered yields nonobvious results.

There is no showing of truly unexpected results that are statistically and practically significant and commensurate in scope with the claims

Applicant refers to data in Example 11 of the specification and data obtained from a "grant application" in support of patentability. As an initial matter, the information at pages 29-30 and Attachment A cannot be dispositive, because they were not

properly presented as a declaration under 37 C.F.R. § 1.132. See also M.P.E.P. § 716.01(c).

Furthermore, it is not clear what elements of Example 11 applicant finds nonobvious. M.P.E.P. § 716.02(b) requires evidence of unexpected results to be of both practical and statistical significance. Example 11 compares the effects of injecting a combination of MSCs and EPCs with the effects of injecting each type alone, with Figure 17 indicating that the combination results in a slightly higher ratio of blood flow in ischemic leg tissue 7 days after the injection than either cell alone. However, at 14 days, all three treatments yield statistically identical results. It is not clear either that the difference in flow ratio (~0.27-0.29 for the individual cell types compared to ~0.39 for the combination) or the difference in treatment time is practically significant. More importantly, however, it is not clear that the skilled artisan would have been surprised to learn that injecting a combination of two cell types, both of which were known to treat ischemia, improved the treatment of ischemia. The data in Figure 17 does not demonstrate any synergistic effect; indeed, the effect appears to be less than additive. Unexpected results must be truly unobvious.

To be given substantial weight in the determination of obviousness or nonobviousness, evidence of secondary considerations must be relevant to the subject matter as claimed, and therefore the examiner must determine whether there is a nexus between the merits of the claimed invention and the evidence of secondary considerations. The term "nexus" designates a factually and legally sufficient connection between the objective evidence of nonobviousness and the claimed invention so that

the evidence is of probative value in the determination of nonobviousness. See M.P.E.P. § 716.01(b). Here, no nexus exists. The data in Example 11 represents a single embodiment of the broad claims, i.e. an injection of $1x10^6$ human CD133+ cells (EPCs) and $1x10^6$ human MSCs, the former of which Example 3 indicates are "between 75% and 85%" pure, to treat femoral artery ischemia. (Page 32, line 15; page 43.) The independent claims, on the other hand, are not so limited. They include all tissues, all amounts of both types of cells, cells isolated from all mammals, and EPCs between 75% and 100% pure. Some of the dependent claims further limit these and other parameters of the independent claims, but none of them has the same scope as the data in Example 11.

This rejection would be best addressed by a narrowing of the claims such that they are commensurate in scope with evidence of truly unexpected results that are both practically and statistically significant. No such evidence is currently on record.

No claims are allowed. No claims are free of the art.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is (571)272-1928. The examiner can normally be reached on Monday-Thursday, 9:00am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lora E Barnhart/
Primary Examiner, Art Unit 1651